



# WEST VIRGINIA INTEGRATED BEHAVIORAL HEALTH CONFERENCE

## Implications of the Proposed DEA Regulatory Changes

*Charlotte A. Smith, R. Ph., M.S., Senior Regulatory Advisor,  
PharmEcology Services, WM Healthcare Solutions, Inc.*

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# Drug Enforcement Administration

- Responsible for enforcing the Controlled Substances Act, effective May 11, 1971
- CSA merged more than 50 pieces of legislation between 1914 and 1970
- DEA established in 1973 through merger of:
  - Bureau of Narcotics and Dangerous Drugs
  - Office for Drug Abuse Law Enforcement
  - Office of National Narcotic Intelligence
  - Bureau of Customs (partial)
  - Office of Science and Technology (drug enforcement)

<http://www.deadiversion.usdoj.gov/>



# Fundamental Tenets of Controlled Substances Act

- 1. Registration
- 2. Security
- 3. Accountability
  - Inventories
  - Recordkeeping
  - Reporting



# Purpose of the Controlled Substance Act

- Improve control over the manufacture, distribution, and dispensing of controlled substances
- Providing a “closed” system for legitimate handlers of controlled substances
- “Reverse Distribution” has been a challenge for DEA from a regulatory perspective
- Safe and Responsible Drug Disposal Act of 2010 presents latest challenge with respect to disposal by the “ultimate user” who is out of the DEA closed loop



# What is a Controlled Substance?

- Drugs or other substances that have a potential for abuse or dependence
- List of drugs, chemicals defined as controlled substances has expanded greatly in the past 30 years
  - <http://www.deadiversion.usdoj.gov/schedules/index.htm>  
<http://www.deadiversion.usdoj.gov/schedules/schedules.htm>
  - Exempted lists:  
[http://www.deadiversion.usdoj.gov/schedules/exempt/exempt\\_list.htm](http://www.deadiversion.usdoj.gov/schedules/exempt/exempt_list.htm)
- Formerly narcotics (opium-based pain relievers); now based on drugs favored by illicit drug users including testosterone



# Schedules of Controlled Substances: I - V

- Schedule I (CI)
  - No accepted medical use in the U.S.
- Schedule II (CII)
  - High abuse potential
  - Transfer requires a tri-part Form 222 Order Form
- Schedules III – V (CIII – CV)
  - Decreasing abuse potential
  - Tylenol c Codeine, anabolic steroids (testosterone), Valium, Robitussin AC



# The Proposed DEA Regulations

- Requirements to govern the secure disposal of controlled substances by both DEA registrants and ultimate users
- Regulations will implement the Secure and Responsible Drug Disposal Act of 2010
- Expands options for take-back events, mail-back programs, and collection receptacle locations
- Law enforcement can remain involved at all 3 levels





# The Proposed DEA Regulations

- Authorized manufacturers, distributors, reverse distributors, and retail pharmacies can voluntarily administer mail-back programs and maintain collection receptacles.
- Retail pharmacies authorized to maintain collection receptacles at long term care facilities
- Reorganizes and consolidates regulations on disposal and role of reverse distributors



# Factors & Goals Considered by DEA

- Public health and safety
- Ease and cost of program implementation
- Participation by various communities
- Encourage a variety of methods for collecting & destroying CS securely
- Decrease the amount of CS introduced into the environment
- Decrease the supply of unused CS in the home, reducing the risk of diversion or harm



# Healthcare Sectors Impacted by Proposed DEA Changes

- **Registrant Disposal**
  - Manufacturers
  - Distributors
  - **Retail Pharmacies**
  - **Hospitals**
  - **Reverse Distributors**
- **Non-Registrant Disposal**
  - “Ultimate User” collection programs, including law enforcement
    - Mail-back
    - Receptacles (kiosks)
    - Single day events
  - “Ultimate User” long term care facilities (LTCFs)
    - Receptacles provided and managed by retail pharmacies



# Review of all Disposal Regulations

- Consistent disposal procedure for each registrant category
- Modify existing DEA form 41 to record the destruction of CS both in the closed system and collected from ultimate users



DHS Form No. 115-6007	<b>DEPARTMENT OF JUSTICE / DRUG ENFORCEMENT ADMINISTRATION</b> <b>REGISTRANTS INVENTORY OF DRUGS SURRENDERED</b>	PACKAGE No. _____
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The following schedule is an inventory of controlled substances which is hereby surrendered to you for proper disposition.

FROM: (Include Name, Street, City, State and ZIP Code in space provided below.)

Signature of applicant or authorized agent

Registrant's DEA Number

Registrant's Telephone Number

NOTE: CERTIFIED MAIL/Return Receipt Registered is REQUIRED FOR SHIPMENTS OF DRUGS VIA U.S. POSTAL SERVICE. See instructions on reverse of form.

NAME OF DRUG OR PREPARATION	Number of Containers	CONTENTS (Number of doses, tablets, capsules, or other units per container)	Controlled Substance Code (See Table)	FOR DEA USE ONLY		
				DISPOSITION	QUANTITY	
				GMS.	MGS.	
1						
2						
3						
4						
5						
6						
7						
8						
9						
10						
11						
12						
13						
14						
15						
16						
17						
18						
19						
20						
21						
22						
23						
24						

The controlled substances surrendered in accordance with Title 21 of the Code of Federal Regulations, Section 1307.21, have been received in \_\_\_\_\_ packages purporting to contain the drugs listed on this inventory and have been: \* (1) Forwarded tape-wrapped without opening; (2) Destroyed as indicated and the remainder forwarded tape-wrapped after verifying contents; (3) Forwarded tape-wrapped after verifying contents.

DATE \_\_\_\_\_ 19\_\_\_\_

DESTROYED BY: \_\_\_\_\_

\*\* If the one (1) box not applicable.

WITNESSED BY: \_\_\_\_\_

**INSTRUCTIONS**

1. List the name of the drug in column 1, the number of containers in column 2, the size of each container in column 3, and in column 4 the controlled substance unit(s) of each unit in column 5. e.g., morphine sulfate tabs, 8 (plus 500 tabs, 3 (plus 128 mg.) in ampoules).
2. A.S. (See instructions on reverse of form.)

**Exhibit 5.6: DEA Form 41**



# Changes in CSA

- Delete 21 CFR 1307.12 Distribution to supplier or manufacturer and 21 CFR 1307.21 Disposal of controlled substances
- New Part 1317 will expand available disposal options, establish nationwide standards for disposal of CS, outline process and procedure for the disposal of CS by registrants, ultimate users, and long term care facilities.



# Methods of Destruction

- New proposed standard of destruction: non-retrieveable
- Intended to allow public and private entities to develop a variety of destruction methods
  - Secure, convenient, responsible, consistent with preventing diversion
  - Must meet all other applicable regulations



# Importance of Reverse Distribution System

- Recommended by DEA as a method of properly disposing of outdated and unwanted controlled substances
- Transfer between registrants
- RDs will become even more important under the proposed regulations
- Existing return and recall regulations for RDs will change





# Current Definition of Reverse Distributor

- Definition: 21 CFR 1300.01(b)
- "a registrant who receives controlled substances acquired from another DEA registrant for the purpose of returning unwanted, unusable, or outdated controlled substances to the manufacturer or the manufacturer's agent, or, where necessary, processing such substances or arranging for processing such substances for disposal."
- Must follow 21 CFR 1307.21 Procedure for disposing of controlled substances



# Involvement of Law Enforcement & “Collectors”

- Law enforcement may voluntarily hold take-back events and administer mail-back programs
- Non-law enforcement “collectors”
  - Manufacturers, distributors, reverse distributors, retail pharmacies
  - Mail-back program must have and utilize an on-site method of destruction
  - Must provide specific mail-back packages
  - CS collected by “collectors” may not be counted or inventoried



# Commingling of CS and Non-CS

- Controlled and non-controlled substances may be collected together as long as the requirements for CS collection are followed



# Changes in Law Enforcement Collection

- May transfer CS from a collection event to RDs for destruction, with proper recordkeeping
- May conduct mail-back programs using packaging described in the proposed regulations
- May partner with a 3<sup>rd</sup> party for funding, dissemination, production or other non-collection activity



# Transfer of CS from Law Enforcement to RDs Unclear

- DEA recommends law enforcement agencies keep a record of any transfer of CS to RDs for destruction
- Can this transfer be done by common carrier?
- What level of documentation is required?
  - At the drug level?
  - At the package level?
- What records must be kept by the reverse distributor?



# Collectors

- Manufacturers, distributors, reverse distributors, retail pharmacies may apply to modify their registration to be a collector
- Retail pharmacies co-located within hospitals may be registered as collectors, but registered hospitals may not due to security concerns
- Must apply for modification in registration which will appear on registration as “Collector”
- If registrant ceases collection, must modify registration to indicate change



# Activities Allowed by Collectors

- Receive mail-back packages from ultimate users if collector has and uses an on-site method of destruction
- Install, manage, and maintain collection receptacles at authorized locations
- Promptly dispose of sealed inner liners and their contents
- The Disposal Act did not provide DEA the authority to register persons specifically for collection and disposal so DEA is restricted to operating within existing registration framework



# Required Recordkeeping

- Maintain an inventory of all inner liners and mail-back packages and maintain records on use and destruction
- Once sealed, inner liners and mail-back packages shall not be opened, ex-rayed, or otherwise penetrated
- The contents may not be individually handled, counted, inventoried or otherwise “discerned”
- Exempt from ARCOS and order form requirements





# Use of Reverse Distributors

- Law enforcement agencies and authorized collectors may use reverse distributors for the purpose of destruction
  - Law enforcement - regardless of mail-back, receptacle, or collection event
  - Collectors - for collection receptacles only
- Distributors may also acquire CS from collectors for purpose of destruction



# Take-Back Events

- To be conducted only by law enforcement agencies
  - Highly publicized
  - Held at easily accessible locations
  - Do not have the same security controls as permanent collection locations
  - More vulnerable to diversion
- Private entities or community groups may continue to partner with law enforcement



# Take-Back Events

- Law enforcement agency shall appoint a full time officer to oversee the collection
- Law enforcement must maintain control and custody of the collected substances throughout the process
- Each event should have at least one receptacle for permitted substances
  - Securely locked, outer shell, removable inner liner
- No volunteer may handle or touch the CS at any time
- Therefore, no pharmacists may sort CS from other drugs



# Restriction on Take-back Volunteers

- Will restrict the waste vendor from managing any drugs on-site
  - In some states, will cause the entire load to become hazardous waste, including CS
- Will cause huge amounts of drugs to be managed by law enforcement as controlled substances



# No Option for Data Collection

- Well intentioned to reduce opportunity for diversion
- Provision should exist for specific exemption based upon strict protocols for research
- Reverse distributors are required to document receipt and disposal of individual dosage forms of controlled substances and will need an exemption to comply



# Mail-Back Programs

- Law enforcement
- Registered manufacturers, distributors, reverse distributors, or retail pharmacies
  - Authorized as collectors
  - Have and utilize an on-site method of destruction at their registered location
- Packaging: postage paid, preaddressed, nondescript, tamper-evident, tear resistant, unique ID number, instructions for use



# On-Site Destruction Required for Mail-back Programs

- Current proposed regulations requires any entity conducting a mail-back program to have on-site destruction capabilities
- Only a handful of DEA registrants have such capability reducing competition
  - Incineration facilities who are registered as reverse distributors
- Consider opening up mail-back option for reverse distributors who are managing retail kiosk returns and law enforcement returns



# Collection Receptacles

- May be placed at law enforcement agencies, or registered manufacturers, distributors, reverse distributors, or retail pharmacies (including LTCFs serviced by pharmacies)
- May NOT be placed at libraries, community centers, hospitals (except for retail pharmacies located within hospitals)





# Collection Receptacles

- Permanent outer container with a removable inner liner
- Opening large enough to allow contents to be added, small enough to prevent removal of the contents
- Opening must be capable of being locked when authorized employee is not present unless monitored by LTCF personnel



# Collection Receptacles cont.

- Sign indicating only Rx and OTC drugs are acceptable (No illicit drugs)
- Securely fastened to permanent structure
- Immediate proximity to Rx storage area and authorized employee
- Access restricted to authorized employees



# Inner Liner Requirements

- Waterproof, tamper-evident, tear resistant
- Removable and sealable immediately upon removal without emptying or touching the contents
- Contents shall not be viewable from outside when sealed
- Size must be marked on outside – 5 gallon, etc.
- Must bear a permanent, unique ID number enabling tracking



# Removal of Inner Liner

- Performed by 2 authorized employees
- Distributor or RD may remove for the purpose of destruction
  - Either destroy the inner liner and contents or store at location in CII security level
- Practitioner collectors: Either destroy on-site or deliver inner liner by common or contract carrier to a distributor or RD for destruction or RD can pick up or request assistance from Special Agent in Charge



# RDs Required to Destroy the CS Within 14 days of Receipt

- Incinerators are hundreds and sometimes thousands of miles away requiring load consolidation
- Not reasonable for 2 employees to accompany the load
- Need to approve options already in place for hired off-duty police, etc. to witness the burn



# RDs Required to Store at Schedule II Security Level

- Schedule II security requires a vault that meets specific DEA requirements
- Schedule II controlled substances make up a very small percentage of drugs prescribed to patients
- The requirement to store potentially large shipments of returned pharmaceuticals in current Schedule II vaults may deter RDs from participating
- Storage in the CS cage for Schedules III through V should be considered



# Additional Challenges of the Rule

- Lack of provision for caregiver to be in possession for disposal
- Lack of specific options for disposal by healthcare facilities
- Requirement of hospitals to use Form 41
  - Currently document electronically



# Impact on Long Term Care Facilities (LTCFs)





# Proposed: Long Term Care Facilities (LTCFs)

- Authorized retail pharmacies may place collection receptacles in LTCFs
- The authorization must specify the physical location of the LTCF
- LTCFs are permitted to dispose of CS on behalf of an “ultimate user” that resides or has resided at the LTCF ONLY through a collection receptacle maintained by a retail pharmacy
- Proposed rules apply to partial, un-administered doses
- Receptacle must be in a secured location or monitored by personnel of the LTCF



# Additional Receptacle Security Measures

- Collection receptacle securely fastened to a permanent structure such as wall, floor, or immovable counter top
- Access to the inner liner is restricted to authorized employees of the retail pharmacy
- Removal of the inner liner shall be performed by or under the supervision of at least two authorized employees of the authorized collector, i.e. the retail pharmacy
- The authorized collector shall promptly:
  - Destroy the inner liner and its contents
  - Store the inner liner and its contents at the collector's registered location in a manner consistent with the security requirements for Schedule II controlled substances until prompt destruction can occur



# Additional LTCF Aspects

- An LTCF MUST dispose of CSs ONLY into an authorized collection receptacle at the LTCF
- LTCFs are NOT permitted to deliver or transfer the CS off-site (**no longer able to take to a DEA disposal event**)
- If the LTCF does not have access to an on-site collection receptacle, they are not permitted to dispose of a CS on behalf of an ultimate user
  - The ultimate user or persons lawfully entitled to dispose of the deceased's property should dispose of those CS
  - DEA believes LTCFs do not have in place physical security controls for CSs
  - LTCF residents may utilize any other disposal method



# Restricting Disposal to Collectors in LTCFs

- Assumes the LTCF provider pharmacies are willing to become “collectors” for their LTCFs
  - Who pays for the destruction of the resident’s medication?
  - How is destruction managed prior to these receptacles being available?
  - What about LTCFs who do not have a pharmacy “collector” in their area?
- **Recommendation:**
  - Continue to allow flushing until collectors become available
  - Consider allowing LTCFs to render CS non-retrievable, as in hospitals
  - Allow LTCFs to utilize a mail-back program, especially if no retail pharmacies offer collection services



# Access to the Inner Liners

- Two employees of retail pharmacy must be present to remove and replace inner liner
  - Deliveries are typically done by one employee. How will extra cost be covered?
- Only employees of retail pharmacy can access inner liner
  - What happens if liner fills up between deliveries?
- **Recommendations:**
  - Have nursing supervisor witness and sign on removal of inner liners the second witness
  - Enable Director of Nursing and Assistant Director of Nursing to remove and replace inner liner and store in a secured location only accessible by management



# Proposed DEA Alternatives to the Collection Receptables: Unrealistic

- The concept that LTCF *residents* can utilize an alternative method of destruction is not reasonable and DEA should be informed this is not a realistic alternative
- Likewise, when a resident dies, handing off their controlled substances to the next of kin for disposal is also unwise and not realistic
- **Recommendation:**
  - DEA should seek a better understanding of the current record-keeping maintained by nurses at LTCFs for controlled substances



# Commingling of Controlled Substances with other Pharm Waste at the LTCF

- DEA allows for commingling of controlled and non-controlled substances in the receptacles
  - Inner liners would fill up too quickly
  - Most states consider LTCFs to be businesses and therefore subject to RCRA; virtually no controlled substances used in LTCFs are RCRA
  - Delivery of RCRA hazardous waste to the retail pharmacy and beyond would violate state and federal hazardous waste regulations
- **Recommendation:**
  - Continue to segregate controlled substances from non-controlled substances as is currently the practice
  - Manage non-controlled substance pharmaceutical waste as RCRA or segregate into hazardous and non-hazardous, using the appropriate waste vendor for each waste stream



# SUMMARY

- The proposed DEA regulations offer additional options for disposal of unwanted consumer controlled substances
- Some aspects of the proposed regulations appear to be problematic
- Hopefully DEA will make modifications based on the many comments submitted by interested parties





# Questions?

Charlotte A. Smith, R. Ph., M.S.

[csmith@pharmacology.com](mailto:csmith@pharmacology.com)

713-725-6363

